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EXAMINER

PONNALURI, PADMASHRI

ART UNIT PAPER NUMBER

1639

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------|--------------------------------|--|
| Office Action Summary | Application No. 10/018,347 | Applicant(s) TEPER, GABRIEL | |
| | Examiner Padmashri Ponnaluri | Art Unit 1639 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application. -
- 4a) Of the above claim(s) 1-14 and 29-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2001 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/20/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of group II, claims 15-28; and election of following species: a) *Salmonella enterica*, *Salmonella virchow*, and *Salmonella virchow* sub-variant B1-2 (bacteria 248, Table 2), and N is 1000, in Paper filed on 2/2/04 is acknowledged.
2. Claims 1-14, 29-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper filed on 2/2/04.
3. Claims 15-28 are currently being examined in this application.

Priority

4. This application is a 371 of PCT/IL00/00366, filed on 6/22/00, which claims priority to provisional application 60/140,749, filed on 6/25/99.
5. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
8. Claims 15-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.

The instant claim briefly recites a method for typing bacteria present in a sample, the Method comprises: a) incubating the sample with an arrayed library of bacteriophages being categorized into: I) a first category including bacteriophage infective to a first bacteria; ii) a second category including bacteriophage infective to a second bacteria; iii) a third category including bacteriophage infective to a third category of bacteria; and b) identifying bacteriophages being infective to at least one bacteria in said sample; and correlating between an identity of said bacteriophages and identity of bacteriophages of said library known to be infective to bacterial standard, so as to enable typing of said at least one bacteria present in the sample.

The specification discloses library of bacteriophages, which are unique to bacteria. The specification discloses mutant (no clear definition of mutant) bacteriophages useful in typing bacteria. The specification description is descriptive and hypothetical use of known methods of typing bacteria in array format. The specification has not disclosed the instant claimed method of typing bacteria as in the instant claimed method. The specification discloses several different types of bacteriophages are known. And the specification discloses ^{the use of} databases and computer databases in the claimed method. i.e., see table 2 and 3. The specification discloses that the

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typical database result is shown in Table 2. And the table represents the results of the typing of a single bacterial species *S. virchow* (i.e., see page 38).

Example 6 in the specification discloses *Staphylococcus aureus* and coagulase negative staphylococci by a novel phage library. The specification discloses that an API-STAPH test was performed of all the bacteria to determine the API profile. And each type of bacteria (i.e., Different API profile bacteria) is analyzed with a library of phage markers, and such that the positive bacteriophages to the particular bacteria were identified. The bacteria with API profile of 6736150 were marked green and the bacteria with API profile of 6736151 are marked blue.

Thus, the specification discloses that the bacteriophages which are specific to specific bacteria have to be identified priori to the experiment, and have to be marked such that they can be detected. And further the specification has not disclosed typing of unknown bacteria (bacteria present in the sample) in a mixture.

The specification description is directed to the use of specific bacteriophages for typing specific individual bacteria (note that the bacteria are not in a sample as in the instant claims), which clearly do not provide an adequate representation regarding the open ended presently claimed method.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601,

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1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

Although directed to compounds, this holding would be deemed to be applicable to a method; which requires a representative examples of the disclosed method and further specific bacteriophages which are specific for the bacteria present in the sample used in the claimed method and a showing of sufficient identifying characteristics of the different specific bacteriophages to demonstrate possession of the claimed generic(s).

In the present instance, specific bacteriophages which are used to type bacteria which are present in a sample as in the claimed method contains no identifying characteristics.

Additionally, the narrow scope of examples directed to specific bacteriophages to type specific bacteria are clearly not representative of the scope of instantly claimed invention.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 15, 19-20, 22-26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Loessner et al (Applied Environmental Microbiology., June 1990. vol. 56, No. 6, pages 1912-1918).

Loessner et al teach bacteriophage typing scheme for differentiating *Listeria* isolates from dairy products and various other food stuff. The reference teaches the use of 16 different selected

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phages divided into 4 groups has been used in the method. The reference lists all the strains and serotypes of *Listeria* and the bacteriophages used in the method in table 1. The reference further teaches that phages were divided into four groups according to their host ranges (refers to the different category of bacteriophages used in the instant claimed method) (i.e., see page 1914). The reference teaches group I lysed almost all strains (refers to the third category of bacteriophages of the instant claims); and group II lysed primarily members of *L. monocytogenes* (refer to the either first or second category of the instant claimed bacteriophage categories); and group IV bacteriophage were specific for either *L. monocytogenes* or *L. innocua* (i.e., see table 3). The reference teaches results of typing of 511 strains of *Listeria* spp. with respect to species and serovar are presented in table 4. The reference teaches that *L. grayi*, *L. murrayi* were not lysed by any of the phages, and serovar 3 of *L. monocytogenes*, and *L. seeligeri* as well as to serovar 6a of *L. innocua* were resistant to the phages; and strains of serovar 5, i.e., of *ivanaovii* were characterized by their sensitivity to group III phages (refers to the instant claim 'bacteriophages infective to at least one bacteria) (i.e., see table 4). The reference clearly anticipates the claimed invention.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 15-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,447,836 (Wolber et al) and Loessner et al (Applied Environmental Microbiology., June 1990. vol. 56, No. 6, pages 1912-1918).

Wolber et al teach method and compositions for detecting viable bacteria in biological samples (refers to instant claimed method) (i.e., see column 3). The reference teaches that the compositions comprise bacteriophage particles capable of infecting a known host range of bacteria and transducing such bacteria to a readily detectable phenotype (refers to the bacteriophages of the instant claims) (i.e., see column 3). The reference teaches that the method is suitable for detecting most types of bacteria. The reference teaches that the biological samples of interest may be obtained from virtually any source capable of supporting or preserving the bacteria in a viable condition, including patient specimens, water, dairy products, meat products and the like (refers to the instant claim 22) (i.e., see column 3).

The reference teaches that the method of the present invention may be used either for screening samples for the presence of bacteria or for typing bacteria of an unknown strain or species (refers to instant claimed method of typing bacteria). The reference teaches that the

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bacterial typing utilizes a panel of bacteriophage having a distinct (refers to the instant claim first category or second category of bacteriophages) or overlapping host ranges (refers to the third category of bacteriophage of the instant claims). The reference teaches that the reference method has advantages for bacterial typing because the detection of phage infectivity is very rapid, greatly shortening the overall time required for the assay. The reference teaches that a list of bacterial hosts and bacteriophages capable of infecting such hosts is presented in table 1 (refers to instant claim 23).

The reference teaches that the wild-type bacteriophage obtained from any source may be modified by conventional recombinant DNA technique in order to introduce a desired primary marker gene capable of producing a detectable phenotype of interest (i.e., see column 7) (refers to the instant claim mutants of known bacteriophages). The reference teaches host range specificity of specific phage (p22) in mixed cultures. The reference teaches that to accommodate large number of individual samples, the procedure was performed in a sterile 96-well microtitre dish (refers to the instant claim library of arrayed bacteriophages and the solid support carrying the plurality of individual bacteriophages). And the reference further teaches the use of a small amount of fluorescent dye concentrate was added to each sample (refers to the assay reagent of the instant claims).

The claimed invention differs from the prior art teachings by reciting the use of three different categories of bacteriophages in typing two different bacteria present in a sample. Wolber et al teach modified bacteriophages in typing bacteria in a sample and the array assay format. Wolber et al has not taught three different categories of bacteriophages useful in typing bacteria present in a sample.

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Loessner et al has been discussed supra. Loessner et al teach bacteriophage typing scheme for differentiating *Listeria* isolates from dairy products and various other food stuff. Thus, it would have been obvious to one skilled in the art at the time the invention was made to use different categories of bacteriophages to type bacteria present in a sample, because Loessner et al teach the use of different categories of bacteriophages to type bacteria present in a sample and Wolber et al teach methods of using mutant bacteriophage in typing bacteria present in a sample. A person skilled in the art would have been motivated to combine the methods of Loessner et al and Wolber et al so that the contaminant bacteria in food be detected in a very rapid and greatly shortening the overall time required for the assay.

Conclusion

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

Pp
14 May 2004


PADMASHRI PONNALURI
PRIMARY EXAMINER